NanoAssemblr™ Ignite/Ignite+ systems

Advance, scale and simplify LNP formulation

cytiva

A smarter path to clinical readiness

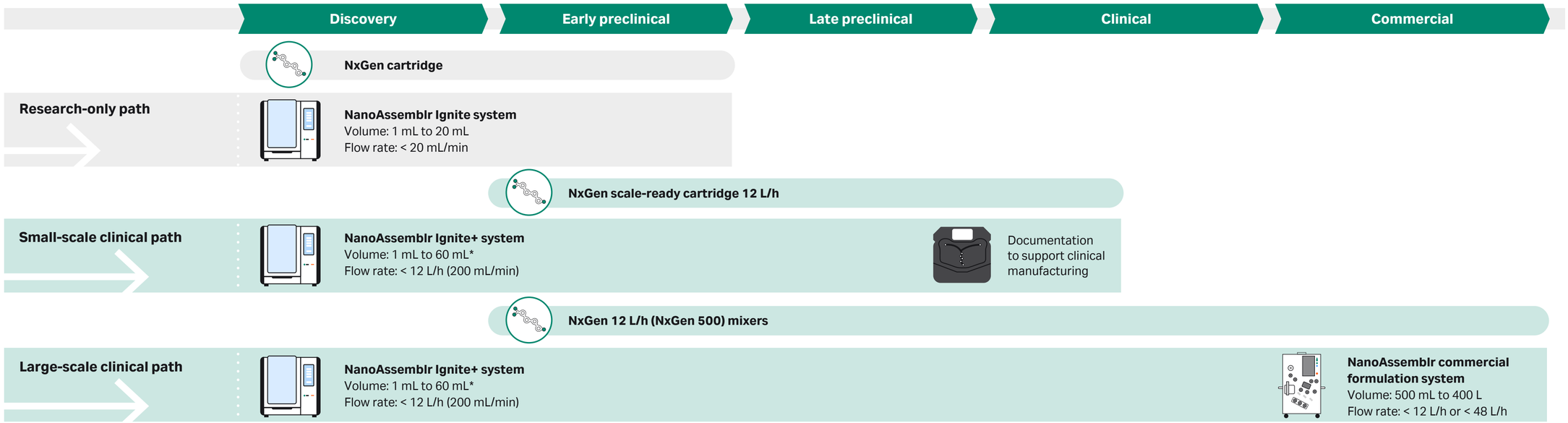
Start small. Think big.

The NanoAssemblr™ Ignite and Ignite+ systems are designed to simplify lipid nanoparticle (LNP) formulation and accelerate your genomic medicine research and discovery. The simple, low-volume workflow results in the automated synthesis of nanomedicines requiring minimal setup and operator training for robust and reproducible formulation. Building upon the Ignite system, the Ignite+ platform is designed to help you scale with confidence, accelerating your drug development from early discovery to the clinic.

Global adoption and proven scalability.

- World's first LNP formulation system to market in 2013, now with over 1500 systems installed globally
- NanoAssemblr systems featured in hundreds of peer-reviewed publications and employed in manufacturing of commercial drugs and clinical stage programs
- Directly transfer small-scale process parameters to larger scale systems using the NxGen™ 12 L/h (NxGen 500) mixer

Choose between a research-only path or prepare early for scalable manufacturing



* Using a 1:1 flow rate ratio (FRR)

Proven technology from the start

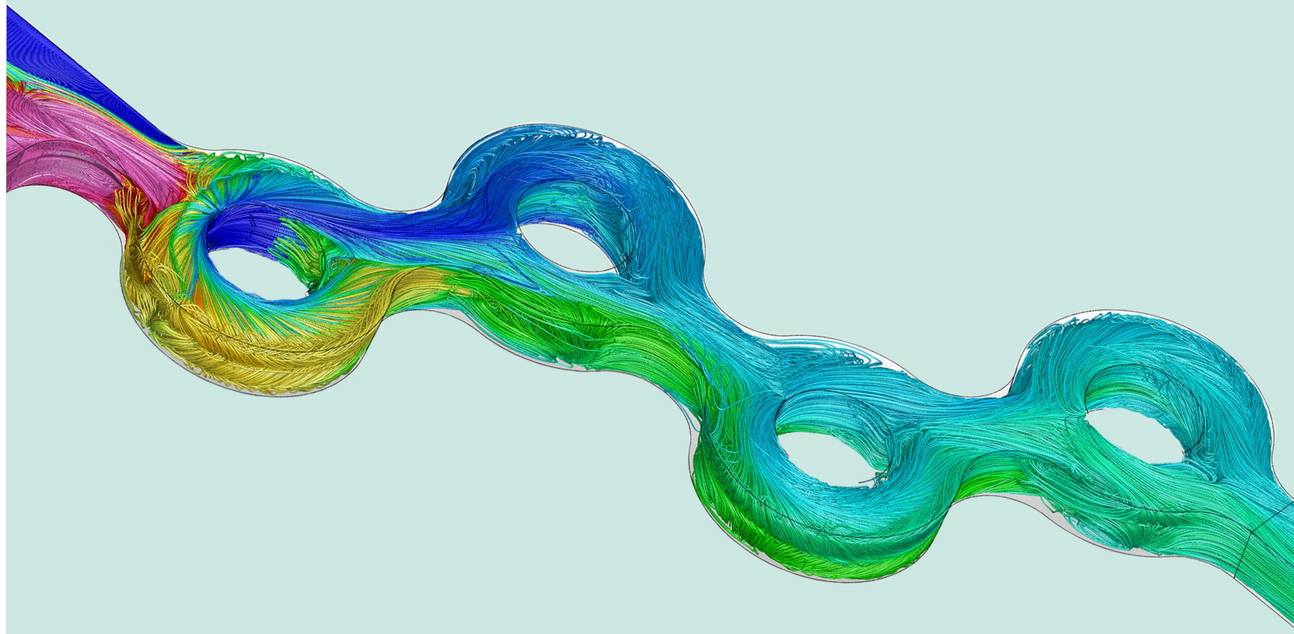
NxGen technology—your foundation for scaling

The Ignite and Ignite+ systems enable the controlled and precise assembly of LNPs by combining optimized precision pumping with the time-invariant mixing of patented NxGen technology.

Conserved geometry ensures consistent and reproducible results to support scaling across different sized mixers to enable a wide range of flow rates appropriate for discovery through to commercial manufacturing.

- The same NxGen mixer is used across our systems to ensure consistent process conditions during scale-up
- Homogeneous high-quality nanoparticles reduce risk as programs advance
- Demonstrated consistent LNP performance from discovery to GMP manufacturing
- Scalable NxGen mixing technology accelerates development timelines

Leveraging computational fluid dynamics, NxGen technology is engineered with a series of precisely arranged toroidal structures that rapidly and gently folds two fluids together, reducing the mixing time and increasing process consistency.



Support your scale-up journey with the Ignite+ system

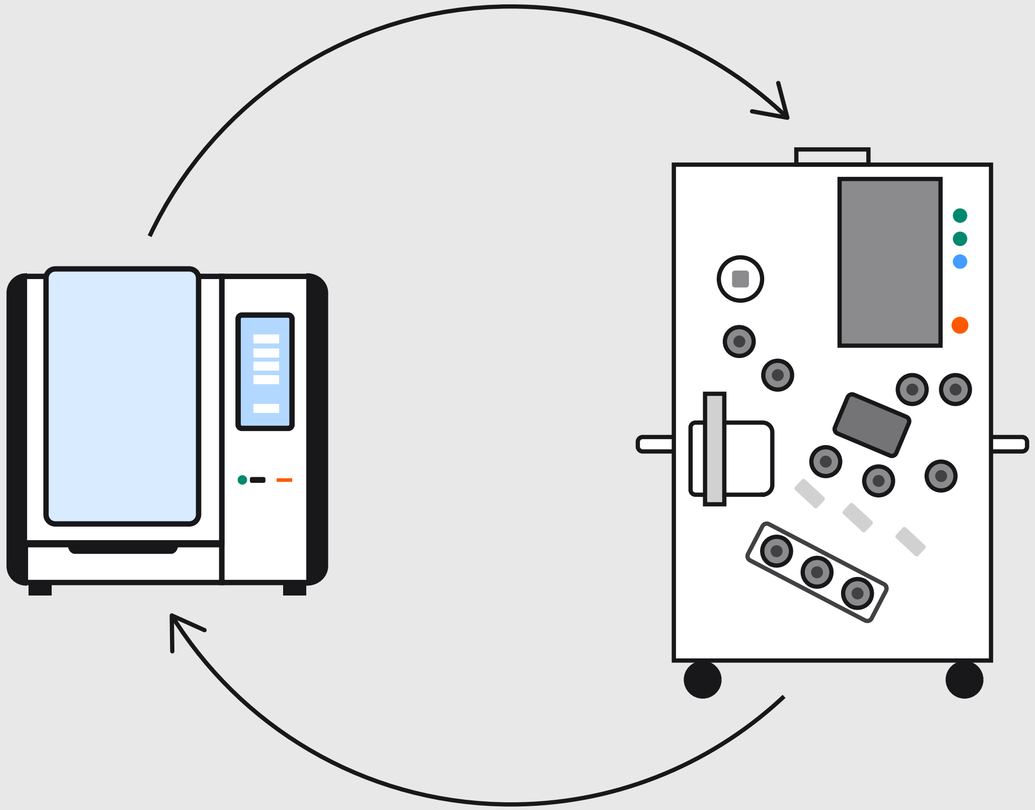
Reliable scale-up. Minimal risk.

The Ignite+ system extends the capabilities of the Ignite platform to support later-stage preclinical activities and process development. Equipped with the NxGen 500 cartridge or NxGen scale-ready cartridge 12 L/h, Ignite+ shares flow rates and mixer geometry with the NanoAssemblr Blaze and NanoAssemblr commercial formulation systems, enabling 1:1 transfer of critical process parameters (CPPs) between systems with minimal process redevelopment.

With an increased batch capacity of up to 60 mL (undiluted), Ignite+ enables early development of upstream and downstream processes, including tangential flow filtration (TFF), and expands efficacy and toxicity testing for small-animal models and larger species, including non-human primates (NHPs).

- Shared flow rates and mixer geometry with the NanoAssemblr commercial formulation system allows simplified transfer of processes between systems
- Develop clinically relevant processes at economical mL scale with the rapid, convenient Ignite+ workflow before scaling up
- Scale down late-stage clinical or manufacturing processes to the Ignite+ system for faster, cost-effective troubleshooting
- All Ignite and Ignite+ cartridges are validated for single use but can now be reused, providing flexibility across diverse workflows and program needs

The NxGen scale-ready cartridge 12 L/h is gamma irradiated, enabling toxicity testing, early-phase evaluations, and small-scale clinical trials (see page 5).



NxGen 12 L/h (NxGen 500): shared mixer geometry allows for 1:1 transfer of parameters between systems

Scale-ready cartridge expands application of Ignite+ system

From discovery to clinic, on one system

The Ignite+ system supports a smooth path to the clinic using the NxGen scale-ready cartridge 12 L/h, designed with GMP in mind for preclinical and clinical development. The cartridge is gamma irradiated and supplied with full material traceability and quality documentation, streamlining scale up and providing the assurance needed for toxicity testing, early-phase evaluations, and small-scale clinical studies.

These features and documentation help reduce risk, support regulatory readiness, and maintain the same workflow on the Ignite+ system throughout development for applications including cell and gene therapy and personalized cancer therapy.

- Gamma-irradiated (25.0 to 45.0 kGy)
- USP <87> & ISO 10993-5 biocompatibility tested
- Animal origin free (AOF) or in compliance with EMA/410/01 rev.3
- Full material lot traceability
- Extractables tested and data available upon request
- Double bagged and packaged in a cleanroom environment

Consistent RNA-LNP physicochemical characteristics across scales

The following data using self-amplifying RNA (saRNA)-LNP formulations demonstrates consistent physicochemical characteristics across scales, showcasing reproducibility and maintenance of CPPs during scale-up.

Table 1. Formulation conditions for scaling. A SARS-CoV-2 saRNA-LNP vaccine was used as a representative system to model the drug development scale-up journey.

Step of scale-up journey	NanoAssemblr system	NxGen mixer	Total flow rate	Batch volume	RNA encapsulated
1	Ignite+	NxGen cartridge	12 mL/min	30 mL	1.1 mg
2	Ignite+	NxGen 500 cartridge	6.9 L/h	30 mL	1.1 mg
3	Ignite+	NxGen 500 cartridge	12 L/h	30 mL	1.1 mg
4	Blaze	NxGen 500 cartridge	6.9 L/h	30 mL	1.1 mg
5	CFS	NxGen commercial flow kit 12 L/h (NxGen 500)	12 L/h	100 mL	3.3 mg
6	CFS	NxGen commercial flow kit 48 L/h	48 L/h	100 mL	3.3 mg

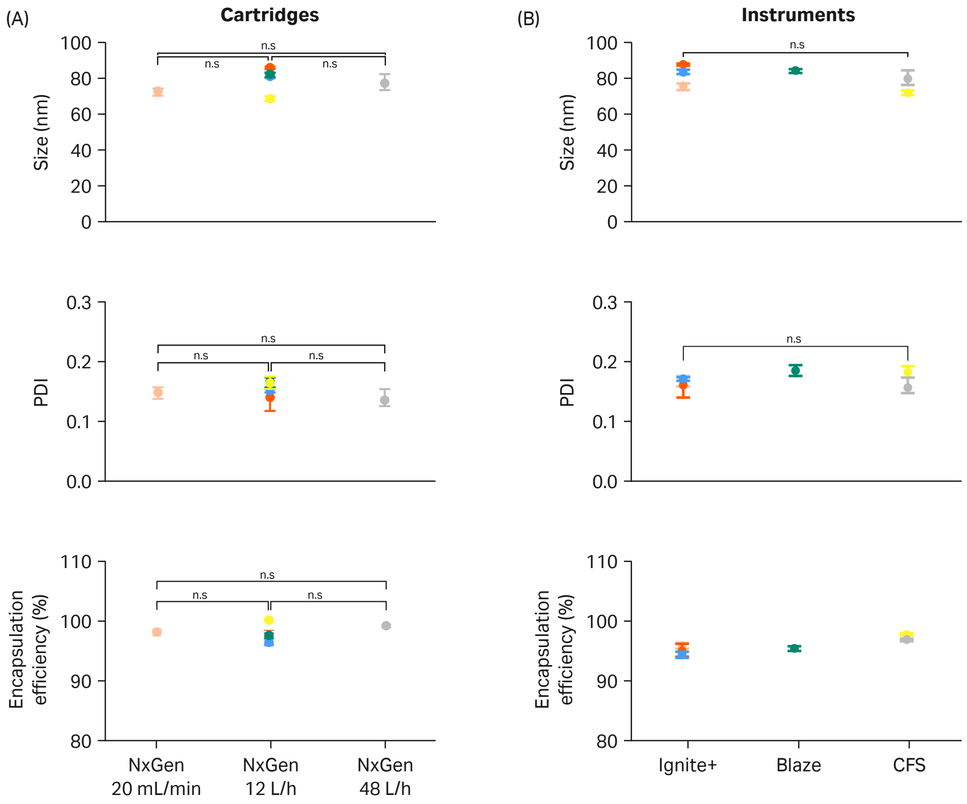


Fig 1. Consistent CQAs were observed following downstream processing. LNP size, polydispersity index (PDI), and encapsulation efficiency (EE%) post-formulation, dilution, TFF, and sterile filtration are consistent across a range of flow rates and cartridges on the NanoAssemblr Ignite+, Blaze, and commercial formulation system (CFS) systems.

Accelerate formulation development with Cytiva lipids

Research-use and clinical ionizable lipids and formulations

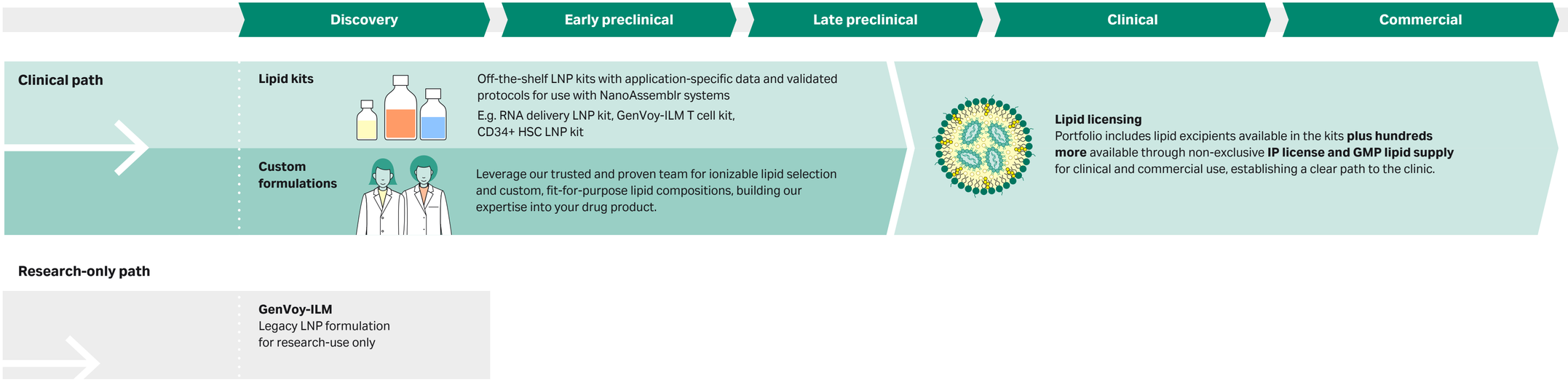
Progress lead candidates quickly through preclinical stages using **ready-to-use kits** or **custom LNP formulations** containing our ionizable lipid mixes. Our lipids can be licensed for clinical development and commercial use, accelerating transitions from discovery to commercialization.

Our lipids employ **unique and differentiated structures** that enable design flexibility and freedom to operate (FTO) for a wide range of applications. A library of **over 200 diverse lipids** is accessible through off-the-shelf kits and custom formulation services, supporting smooth progression from early R&D to clinical and commercial programs.

Cytiva's differentiated ionizable lipids

Common ionizable lipids (MC3, ALC-0315, SM-102)

Cytiva proprietary ionizable lipids



Expertise, support, and end-to-end solutions

Comprehensive genomic medicine solutions

NanoAssemblr systems are part of a complete mRNA workflow and part of our comprehensive genomic medicine solutions. Innovators of advanced therapies are developing LNPs to deliver mRNA and oligonucleotides to enable non-viral gene editing that reduces the risk of off-target edits. Gene-editing by LNPs are being applied to developing *in vivo* and *ex vivo* cell therapies, sometimes in conjunction with viral vectors.

The field is rapidly evolving, with shifting standards and increasing complexity. With our expertise, technology, and BioPharma Services, we'll help you navigate the landscape.

People

- Global team with nanomedicine expertise to support discovery through development
- Dedicated R&D teams continually innovating nanomedicine technologies
- Global network of field service engineers provides quick and effective maintenance and upgrades

End-to end manufacturing technology

- Cell therapy
- Oligonucleotides
- mRNA
- Viral vectors

BioPharma Services

- Comprehensive nanomedicine development services
- Analytical development
- GMP manufacturing of RNA-LNP drug products
- Regulatory support

Ordering information

Instruments	Product code
NanoAssemblr Ignite system	NIN0001
NanoAssemblr Ignite+ system	1001413
NanoAssemblr Ignite+ Upgrade Kit	1001409

Cartridges	Size	Product code
NxGen cartridge	100 pack	NIN0061
NxGen dilution cartridge	50 pack	NIN0063
NxGen 500 cartridge (12 L/h)	50 pack	1001397
NxGen 500D cartridge (12 L/h)	25 pack	1001399
NxGen scale-ready cartridge 12 L/h	25 pack	2987729

Reagent kits	Lipid mix	Product code
GenVoy-ILM T cell kit for mRNA	3 mL	1001144
	6 mL	1001161
CD34+ HSC LNP kit	2 mL	1005000
RNA delivery LNP kit	3 mL	1002569
	6 mL	1002471
GenVoy-ILM reagent	2 mL	1002763
	5 mL	1002769

Heating packages	Product code
NanoAssemblr Ignite heating controller package	NIN0067
NanoAssemblr Ignite+ heating controller package	1001403

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For local office contact information, visit cytiva.com/contact

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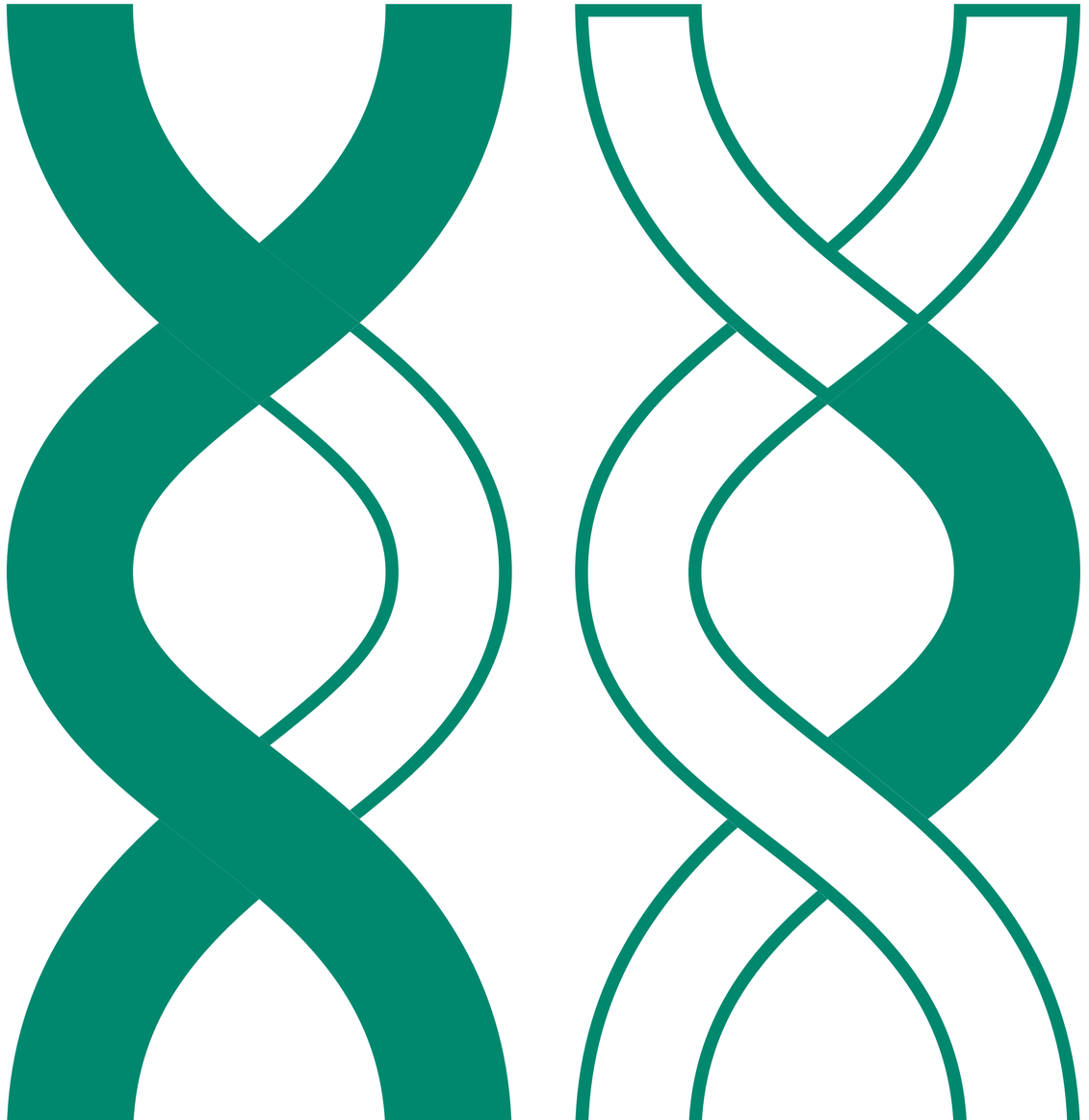

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